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Can monitoring exhaled nitric oxide levels in outpatients improve the management of children with asthma?

Submission date 11/12/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/07/2007	**Overall study status** Completed	
Last Edited 16/02/2015	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
Can monitoring exhaled nitric oxide levels in outpatients improve the management of children with asthma?

Acronym
Exhaled nitric oxide study

Study objectives
The aim of this study is to explore whether monitoring exhaled Nitric Oxide (eNO) levels in outpatients improves the management of children with asthma using a pragmatic experimental design.

The specific objectives are:
1. To determine whether using eNO levels in outpatients to direct therapy allows less inhaled corticosteroid to be used over a year of follow when compared to a control group
2. To determine whether using eNO levels in outpatients to direct therapy reduces the number of exacerbations that require treatment with systemic corticosteroid over a year of follow when compared to a control group

As per 09/02/2012, the anticipated end date has been updated from 31/08/2008 to 31/08/2009 and the target number of participants amended from 150 to 93.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and Southwest Hampshire Local Research Ethics Committee, 18/05/2006, ref: 06/Q1702/9

Study design
Multicentre pragmatic prospective randomised double-blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Asthma

Interventions
Current interventions as of 09/02/2012:
93 subjects aged 6 to 17 years with moderate or severe asthma will be recruited. Their asthma will be stabilised and they will be randomised to the exhaled nitric oxide (eNO) or control group.

All will be assessed every two months for a year. The control group will be managed according to the British Thoracic Society guidelines. In the eNO group, the inhaled corticosteroid doses will be increased in response to elevated eNO levels and reduced if levels are low. Subjects and medical staff involved in managing any exacerbations will be blind to group allocation.

An intention to treat analysis will be undertaken with a comparison of the change in inhaled corticosteroid dose and the number of exacerbations over the one-year follow up period between the two groups. It is expected that the eNO group will use less inhaled corticosteroids and experience less exacerbations.

Previous interventions:
150 subjects aged 6 to 17 years with moderate or severe asthma will be recruited. Their asthma will be stabilised and they will be randomised to the exhaled nitric oxide (eNO) or control group.

All will be assessed every two months for a year. The control group will be managed according to the British Thoracic Society guidelines. In the eNO group, the inhaled corticosteroid doses will be increased in response to elevated eNO levels and reduced if levels are low. Subjects and medical staff involved in managing any exacerbations will be blind to group allocation.

An intention to treat analysis will be undertaken with a comparison of the change in inhaled corticosteroid dose and the number of exacerbations over the one-year follow up period between the two groups. It is expected that the eNO group will use less inhaled corticosteroids and experience less exacerbations.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
An intention to treat analysis will be undertaken with a comparison of the change in inhaled steroid dose and the number of exacerbations over the one-year follow up period between the eNO and control groups.

Secondary outcome measures
1. A per protocol analysis will be undertaken, the dataset for this analysis will be restricted to the subjects whose therapy was directed as per the protocol
2. Subgroup analysis restricted to subjects taking inhaled corticosteroid through a metered dose inhaler with a spacer as it is expected that these will form a more homogeneous analysis group

3. Subgroup analysis focusing firstly on subjects with moderate (400 - 800 mcg/day beclomethasone equivalent) and secondly subjects with severe (greater than 800 mcg/day beclomethasone equivalent) asthma to determine whether results are similar in both groups
4. Subgroup analysis focusing on firstly on atopic asthmatics and secondly non-atopic ones
5. Analyses restricted firstly to only viral associated exacerbations and secondly to exacerbations that are not associated with a viral infection
6. Comparison of the average inhaled steroid use in each group over the last six months of follow up

Overall study start date
12/12/2006

Completion date
31/08/2009

Eligibility

Key inclusion criteria
1. Aged 6 - 17 years
2. Clinical diagnosis of asthma
3. Treatment with at least 400 mcg daily of beclomethasone/budesonide or 200 mcg daily of fluticasone

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
93

Key exclusion criteria
1. Inability to perform lung function or eNO measurement
2. Cigarette smoking
3. Poor compliance with medication
4. Previous life-threatening exacerbations
5. Need for maintenance oral prednisolone

Date of first enrolment
12/12/2006

Date of final enrolment
31/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton University Hospital NHS Trust
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Research Governance
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Sponsor type
University/education

Website
http://www.soton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type

Charity

Funder Name
Sport Aiding Medical Research for Kids (SPARKS) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2013		Yes	No